

Appl. No. : 10/827,101
Filed : April 19, 2004

REMARKS

The claim amendments and remarks herein are responsive to the Examiner's Office Action dated December 15, 2004. Applicant has amended Claims 1, 12, 18 and 25 to more clearly claim the invention. No new matter has been added. Claims 2 and 30 have been cancelled without prejudice. Claims 1, 3-29, 31-33 are currently pending.

Claim objections.

Applicant appreciates the Examiner pointing out that Claim 18 should depend from Claim 12 instead of Claim 11. Claim 18 has been amended to correct this informality.

Claim rejections under 35 U.S.C. § 102.

Claims 1, 5-7, 12-15, 25-28 and 31-33 stand rejected under 35 U.S.C. § 102 as being unpatentable by U.S. Patent No. 3,030,951 to Mandarino. Mandarino discloses the injection of a synthetic polymer through an incised annulus fibrosis for performing an anterior vertebral body fusion. As noted by the Examiner, Mandarino does not disclose performing the procedure in a minimally invasive manner. Accordingly, the following claims have been amended:

Claim 1 has been amended to incorporate the subject matter of dependent Claim 2 to recite:

A method for stabilizing a portion of the spine, comprising the steps of:
accessing a first bony surface on a first vertebra, wherein the first vertebra comprises a vertebral body and at least one bony process;
accessing a second bony surface on a second vertebra, wherein the second vertebra comprises a vertebral body and at least one bony process; and
affixing the first bony surface and the second bony surface with an adhesive medium;
wherein the affixing step comprises minimally invasively joining the first bony surface and the second bony surface and preserves the cortical bone about the first bony surface and second bony surface.

Claim 12 has been amended to recite:

A method for treating a patient, comprising the steps of:
accessing a first bony portion of a first vertebra, wherein the first bony portion is posterior to the vertebral body of the first vertebra;
accessing a second bony portion of a second vertebra, wherein the second bony portion is posterior to the vertebral body of the second vertebra;
engaging the first bony portion and the second bony portion with a medium; and

Appl. No. : 10/827,101
Filed : April 19, 2004

fixing the relative orientation between the first vertebra and the second vertebra by permitting physical or chemical transformation of the medium; wherein

the engaging step comprises minimally invasively joining the first bony portion and the second bony portion.

Claim 25 has been amended to incorporate the subject matter of Claim 30 to recite:

A method of treating a spine, comprising the steps of:

minimally invasively accessing adjacent vertebrae, the adjacent vertebrae comprising a superior vertebra with at least one inferior articular process and a inferior vertebra with a vertebral body and at least one superior articular process,

wherein at least one inferior articular process of the superior vertebra corresponds to a superior articular process of the inferior vertebra; and

positioning the adjacent vertebra from a first spatial orientation to a second spatial orientation; and

securing the adjacent vertebrae in the second spatial orientation by engaging at least one superior articular process of one of the two adjacent vertebrae with the corresponding inferior articular process of the other of the two adjacent vertebrae using a medium.

Because Claims 1, 12 and 25 as amended include a limitation to perform the invention in a minimally invasive manner, it is respectfully submitted that the claims are not anticipated by the prior art and Applicant respectfully requests withdrawal of the rejection of Claims 1, 5-7, 12-15, 25-28 and 31-33.

Claim rejections under 35 U.S.C. § 103.

Claims 2, 9-10 and 30 stand rejected under 35 U.S.C. § 103 as being unpatentable by Mandarino in view of Patent Application No. 2002/0099384 to Scribner et al. As noted by the Examiner, Mandarino does not teach or suggest the performance of the procedure in a minimally invasive manner. Scribner discloses a minimally invasive procedures but teaching is limited to accessing the cancellous bone of a vertebral body through the cortical bone to fill the vertebral body with a filling material. Scribner does not teach the fixation of one vertebra to a different vertebra. This is in opposition to Applicant's invention in amended Claim 1, from which Claims 2, 9-10 depend, which recites an affixing step that preserves the cortical bone about a first bony surface of a first vertebra and a second bony surface of a second vertebra and fixating the two surfaces. Thus, there is no teaching, suggestion or motivation to combine the two references, nor would the invention as claimed result from the combination of these references. Furthermore, it would not have been obvious to one skilled in the art to combine the teachings of Mandarino and

Appl. No. : 10/827,101
Filed : April 19, 2004

Scribner to perform a minimally invasive spinal fixation procedure where the cortical bone is preserved.

With respect to Claim 30, Mandarino discloses a posterior fusion procedure that requires a longitudinal incision over the vertebrae, bilateral exposure of the laminae that is then denuded of soft tissue, followed pouring of a synthetic fluid over the exposed laminae. Col. 3, Lines 9-16. The disclosure in Scribner is limited to access of a vertebral body and does not mention securing of adjacent vertebrae as recited in Claim 25 from which Claim 30 depends. Thus, Applicant contends that there is no suggestion, teaching or motivation to combine these two references, and one having ordinary skill in the art would not have been motivated to combine Mandarino in view of Scribner to teach minimally invasive securing of the articular processes of vertebrae as described in Claim 30.

Furthermore, before the PTO may combine the disclosures of two or more references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Jones*, 958 F.2d 347, 351 (Fed. Cir. 1992). Evidence is required even to support a contention that one skilled in the art would be motivated to combine the references. *Id.* Because Mandarino does not suggest a minimally invasive procedure and Scribner fails to suggest spinal fixation of two vertebrae or preservation of the cortical bone surfaces, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to have performed a procedure for securing adjacent vertebrae using a minimally invasive approach that preserves the cortical bone of the vertebrae. Therefore, Applicant respectfully requests withdrawal of the rejections of claims 2, 9-10 and 30 under 35 U.S.C. § 103.

Claims 4, 16 and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable by Mandarino, as applied in Claim 1, in view of U.S. Patent No. 6,716,216 to Boucher et al. As noted by the Examiner, Mandarino does not disclose the use of cyanoacrylate. While Boucher et al. discloses use of cyanoacrylate in Col. 7, lines 15-18, the teaching of cyanoacrylate in Boucher et al. is limited to its use as a filling material, as shown in Col. 7, lines 3-6, and in particular a compression-resistant material as disclosed in Col. 7, lines 15-18. Because of disparate use of cyanoacrylate in Boucher et al. with respect to Mandarino, these two references do not teach, suggest or motivate one of skill in the art to combine these references to teach a minimally invasive procedure for affixing, engaging or securing two vertebrae as recited in Claims 4, 16,

Appl. No. : 10/827,101
Filed : April 19, 2004

and 30. Accordingly, Applicant respectfully submits that Claims 4, 16 and 29 are not obvious in view of Boucher et al.

Lastly, the Examiner rejected Claims 3, 11 and 18 under 35 U.S.C. § 103 as being unpatentable over Mandarino in view of U.S. Patent No. 6,309,420 to Preissman. According to the Examiner, Mandarino lacks the element of performing a procedure with radiographic visualization while Preissman teaches the use of radiographic contrast agents in viewing bone cements or medium, but the combination of Mandarino and Preissman lacks the element to minimally invasively affix the bony surfaces of two vertebrae while preserving the cortical bone, as recited in amended Claim 1 from which Claims 3 and 11 depend, or to minimally invasively engage the bony surfaces as recited in amended Claim 12. Furthermore, Examiner has not indicated any evidence to support the finding that one of skill in the art would be motivated to combine these two references, as required by caselaw. *Id.* Therefore, Applicant believes Claims 3, 11 and 18 are patentable over the art of record.

Terminal Disclaimer/Double Patenting

The Examiner rejected Claims 1-2, 4-20, 22-29 and 31-33 under the judicially created doctrine of Double Patenting. The Examiner asserted that the Claims were not patentably distinct from Claims 1-4, 6, 9, 11, 14 and 15 of the commonly-owned U.S. Patent No. 6,723,095 to Hammerslag ("'095 patent").

The Examiner also asserted that Claims 3 and 21 were not patentably distinct over Claim 6 of the '095 patent in view of Preissman (US 6,309,420), and Claim 30 is not patentably distinct over Claim 6 of the '095 patent in view of Scribner et al (US 2002/0099384).

While Assignee does not acquiesce to the grounds of the rejected claims, a Terminal Disclaimer in accordance with 37 C.F.R. § 1.321(c) is filed herewith in order to promptly resolve the issue of this objection.

Appl. No. : 10/827,101
Filed : April 19, 2004

CONCLUSIONS

For all the foregoing reasons, Applicant respectfully submits that all of the Examiner's rejections have been overcome and earnestly requests an allowance of all pending claims. If the Examiner believes that a telephonic conference would expedite the examination of this application, the Examiner is invited to contact the undersigned. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 2/9/05

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